Drug assessment at a glance: A26-19[1]

Ivosidenib (acute myeloid leukaemia)

5 August 2026

[1] This is a courtesy translation of the summary provided as a service by IQWiG. For further information on the subject matter and the result of the assessment, please refer to the dossier assessment for Project A26-19. The G-BA decides on the added benefit.

Research question for the benefit assessment

Population	Adults with newly diagnosed AML with an IDH1 R132 mutation for whom standard induction chemotherapy is not suitable
Intervention	ivosidenib + azacitidine
Comparator	venetoclax in combination with azacitidine or venetoclax in combination with decitabine
Outcomes	At least one patient-relevant outcome

Overview of positive and negative effects

	Size of the effects		Informative value of the effects	
Mortality	∅		–	
Morbidity	∅		–	
Symptoms	∅		–	
Health-related quality of life	∅		–	
Side effects	∅		–	
	∅	No (suitable) data	–	Not applicable
	↔	No advantage or disadvantage	★	Low
	↑ / ↓	Small advantage/disadvantage	★★	Moderate
	↑↑ / ↓↓	Moderate advantage/disadvantage	★★★	High
	↑↑↑ / ↓↓↓	Large advantage/disadvantage		

Overall: No advantage or disadvantage (no suitable data)

Evidence base and noteworthy aspects

- No suitable data were available.

- The data presented on the RCT AGILE were not suitable, as they compare ivosidenib + azacitidine versus placebo + azacitidine. A comparison of ivosidenib + azacitidine with the comparator therapy was therefore not possible.
- The data on indirect comparisons of ivosidenib + azacitidine versus venetoclax + azacitidine, based on the AGILE and VIALE-A studies (venetoclax + azacitidine versus placebo + azacitidine), were not suitable, as the studies were not sufficiently similar to allow for indirect comparisons.

References

Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Ivosidenib (akute myeloische Leukämie); Nutzenbewertung gemäß § 35a SGB V; Dossierbewertung [online]. 2026 [Accessed: 05.08.2026]. URL: https://doi.org/10.60584/A26-19.

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Gemeinsamer Bundesausschuss. Nutzenbewertungsverfahren zum Wirkstoff Ivosidenib (Neubewertung Orphan > 30 Mio: Akute Myeloische Leukämie mit IDH1-R132-Mutation, Erstlinie, Kombination mit Azacitidin) [online]. 2026 [Accessed: 04.08.2026]. URL: https://www.g-ba.de/bewertungsverfahren/nutzenbewertung/1321/.

English translations for this project are published at https://www.iqwig.de/en/projects/a26-19.html and https://www.iqwig.de/en/projects/a26-81.html.

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